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Minimal Important Change for the Visual Analogue Scale Foot and Ankle (VAS FA)

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Highlights

- At least 139 patient reported outcome measures are used in foot and ankle surgery
- There is a notable variance in reliability and validity in the outcome measures
- Minimal Important Change is important in interpreting outcome measure results
- VAS-FA was found to efficiently detect changes in patients undergoing surgery

Abstract (150 words)

Background: Visual analogue scale foot and ankle (VAS-FA) is a patient-reported outcome measure for foot and ankle disorders. The VAS-FA is validated into several languages and widely adopted into use. Nonetheless, minimal important change (MIC) for the VAS-FA has not been estimated thus far.

Methods: The VAS-FA score was obtained from 106 patients undergoing surgery for various foot and ankle complaints. MIC was estimated using an anchor-based predictive method.

Results: The adjusted MIC was 6.8 for total VAS-FA score, and 9.3 for the Pain, 5.8 for the Function, and 5.7 for the Other complaints subscales. The VAS-FA score was found to separate improvement and deterioration in patients' [illegible]

Conclusions: MIC was successfully defined for the VAS-FA in the current study. The VAS-FA can be used to evaluate [illegible] clinical [illegible] and its change. Further research on estimating disease-specific MICs is recommended.

Keywords: minimal clinical change; patient reported outcome measure; foot; ankle; VAS-FA

1. Introduction

Patient-reported outcome measures (PROMs) are clinical outcome assessments used to measure V X E M H F W L Y H V \ P S W R P V D Q G W K H H. Ideally, assessment instruments should be responsive to clinical change, reliable, validated, and scores are repeatable[1,2]. Objective measures, such as radiographs, may not indicate relevant clinical changes in function, health-related quality of life or pain

In orthopaedic surgery, use of PROMs has become more common in recent years[3]. At least 139 clinical outcome assessment scales have been used in foot and ankle surgery[1]. Majority of foot and ankle specialists are reported to use PROMs in their daily work[3]. There is a notable variance in evidence of validity and reliability of scores obtained using different foot and ankle questionnaires[4]. Validated disease-specific and generic instruments are recommended for evaluating treatment outcomes as they can provide valuable information which cannot be obtained in other methods[5]. Nonetheless, there is no clear consensus on the recommendation on which PROMs to use for foot and ankle patients. Therefore, more evidence on the measurement properties of foot and ankle PROMs is needed[4].

The Visual analogue scale foot and ankle (VAS-FA) has been designed to evaluate the subjective outcomes after foot and ankle surgery. It has been validated for both healthy individuals and patients with foot and ankle pathologies[7]. The VAS-FA consists of 20 items completed on a visual analogue scale[7]. Visual analogue scale is known to be easy to use, reliable, and has been validated for pain assessment[8]. The items can be divided into three subscales, including pain, function, and other complaints. The score can be calculated in case of missing answers. The instrument has been well adopted by the orthopaedic foot and ankle community and translated into several languages[3,9,10,11]. The VAS-FA has been reported to compare favorably with other foot and ankle PROMs, such as the Lower extremity functional scale (LEFS), the Western Ontario and McMaster Universities osteoarthritis index (WOMAC), and the American Orthopaedic Foot and Ankle Society (AOFAS) scale[10,12]. Although the

VAS-FA instrument is widely tested for its psychometric properties, the minimal important change (MIC) has not been estimated for the VAS-FA thus far.

MIC can be used to determine clinically significant change from subjective patient-reported score.[13] Although statistical significance is useful in interpretation of change, it is closely connected to the sample size and does not interpret meaningful clinical change in PROMs results.[14] The MIC can be implemented in both clinical and scientific work. MIC indicates the smallest change with clinical meaning in outcome assessment or follow-up. Changes greater than MIC are considered clinically relevant, indicating meaningful change in patient-experienced health status.

The purpose of the present study is to estimate the MIC of VAS-FA using anchor-based predictive modeling method.

2. Methods

Ethics Committee of the Hospital District of Helsinki and Uusimaa approved the study protocol. Patients were recruited to the study face-to-face or via mail before surgery. Patients completed the validated Finnish version[9] of VAS-FA either electronically on a tablet computer or as a paper-and-pen version[15]. Written consent in accordance with the principles of the Declaration of Helsinki was obtained from participants. Study inclusion criteria were as follows: at least 18 years old, full understanding of Finnish, coherence in participating in the study, and preset plan to conduct elective foot or ankle surgery by an orthopedic surgeon. Patients who did not meet the inclusion criteria were excluded from the study. Patients who had completed the VAS-FA on two different occasions with a 6-months interval were included in the final analysis. At the time of the second administration of the VAS-FA, the patients also responded to an anchor item ³+RZ GR \RX UDWH \RXU FXUUHQW IRRW RU E H I R U H V X U J H U \ ´ The anchor item had response categories on a five-level Likert scale I U R P ³1 R W D

LPSDLUHG´ WR ³1RWDEO\ LPSURYHG´ WKLV ³DQFKRU LWHP´ ZDV GHVLJQHG WR FDSW perceived situation of the foot or ankle was improved or deteriorated compared to the situation befor surgery. It was used as an external reference for improvement was used to measure the true change that the patients considered as meaningful.

2.1 Statistical methods

Data is presented as means with standard deviation (SD), medians with interquartile ranges (IQR), numbers with percentages, or 95% confidence intervals (95% CI).

The VAS-FA total score as well as subscale scores were analyzed independently. Patients with complete data on VAS-FA scores in 1st and 2nd administrations as well as in the anchor item were included to the analysis. To examine the relevancy of the anchor item, the VAS-FA total and the score distributions of subscales were examined in five subgroups defined by the anchor item response categories. If average VAS-FA scores were ordered in accordance with the anchor item response category, the anchor question was considered as relevant.

In order to determine the MIC values for VAS-FA and the subscales, the patients were divided into improved and not improved groups using the anchor question answer. The patients that reported that WKHLU IRRW KDG ³1RWDEO\ LPSURYHG´ RU ³,PSURYHG´ ZHU ZHUH FDWHJRUL]HG DV ³1RW LPSURYHG´ VAS-FA total and the subscale scores between WKH ³,PSURYHG´ DQG ³1RW LPSURYHG´ SDWLHQWV ZHUH LQYHVWLJDWHG X-test. P values below 0.05 were considered as statistically significant.

Predictive MIC calculation method was applied in determination of the MIC for the VAS-FA as well as for the subscales. Logistic regression models were created with the VAS-FA score change between the administrations as an independent variable and reported improvement as a dependent variable. The

S U R S R U W L R Q R I W K H ³, P S U R Y-test probability of improvement´ the VAS-FA total score and the values were extracted together with the 95% confidence intervals (CI) for subscales. Furthermore, the MIC values were adjusted to the proportion of improved patients in the sample. The calculation methods have been described elsewhere in more detail.[16,17] R 3.1.6 statistical software was used in the statistical analyses.[18] Calculations and statistical modeling were performed X V L Q J W K H E D V H S D F N D J H R I 5 D Q G ³ manipulation and visualization.[19]

3. Results

A total of 106 patients provided complete data regarding both administrations of VAS-FA scores and the anchor question. Majority of the patients were female (75%, Table 1). The age distribution was wide, 22 to 80 years, with the mean age of 56 years. The mean duration of symptoms before surgery was relatively long, 7.8 years. Forty-six (43%) of the patients had undergone previous surgery. The three most common indications for surgery were hallux valgus (n = 25), hallux rigidus (n = 10, Table II). Two most common procedures were fusion of first tarsometatarsal joint (n = 28), and osteotomy of first metatarsal or tarsal bone (n = 13, Table II).

The average VAS-FA total and subscale scores were ordered according to the anchor response F D W H J R U L H V R I ³ 1 R W D W \ L P S U R Y H G ´ W R ³ P S R W L D E O \ L P S U R Y H G ´ L P S D F W the mean VAS-FA scores indicated towards better outcome (i.e. ³ P S U R Y H G ´ VAS-FA total and all subscales.

$ I W H U G L Y L G L Q J W K H S D W L H Q W V L Q W R V X E J U R X S V R I ³, P S U of the patients were categorized into improved subgroup. The increase in the VAS-FA scores of the improved patients was higher than those of the not improved patients regarding the total and all subscales (Table II). The pretest probability of 0.83 was used in estimation of MIC for the VAS-FA

and each of its subscale (Figures I–VIII). The adjustment for the proportion of improved patients reduced the MIC values (Table II).

4. Discussion

The adjusted MIC values of VAS-FA were similar for the overall score (6.8), and the subscales Function (5.8) and Other complaints (5.7), and slightly larger in Pain subscale (9.3) (Table III). In every subscale and the overall score, the MIC defined in the present study was greater than the minimal detectable change reported in a previous study[9], indicating relevant results. According to the findings of the present study, the VAS-FA effectively separates between improved and unimproved patients.

Patient-experienced health is more difficult to measure than traditional measures, such as radiographic findings. Successful treatment aims to increase the health benefit using different health care modalities. The use of PROMs in clinical orthopaedic trials has increased in the recent years, leading to more research done on PROM scores[2]. The most important properties of PROMs are thought to be validity, reliability, and responsiveness[20], which have been previously reported for the VAS-FA[9 11 12]. In addition to these, defining the MIC is important for clinical use of PROMs to understand the clinical interpretation of score results[13], i.e. to distinguish weather results are, not only statistically significant, but more importantly also clinically relevant.

Estimating the significance of PROM answers in clinical work requires the knowledge of the measurement properties of PROM scores, including MIC. In scientific work, MIC provides additional use for calculating the study power for prospective studies. Change in the points of PROMs can also be used as an endpoint in scientific studies, and only differences greater than MIC should steer decisions to change clinical practice[21]. In clinical practice, knowing the MIC of an outcome measure can provide information on the effect of symptoms or their treatment to patient's subjective quality of life, function,

or pain etc[21]. Change greater than the MIC, for example after surgical treatment, indicates meaningful treatment effect. Further, MIC can be used for screening patients in outpatient control visits for the progress of rehabilitation. Knowing the MIC helps to estimate the clinical gains of a treatment and can be used to demonstrate longitudinal treatment effect to the patient when different treatment options are discussed.

Various statistical methods are used to determine the MIC, including the distribution-based and anchor-based methods[22]. Distribution-based methods utilize statistical distribution and mean score values[23]. Anchor-based methods study the relation of external anchor question and the score values[24]. In the present study, the anchor-based predictive method described by Terluin et al was used[16]. Predictive modeling method has been reported to be more precise when compared to another often-used method, the receiver operating characteristic (ROC) analysis[16]. Furthermore, adjustment of the MIC values to the proportion of the improved have been proposed to improve the accuracy of MIC estimates[17].

Despite not being validated and holding several pitfalls, American Orthopaedic Foot and Ankle Society (AOFAS) score is the most commonly used foot and ankle score[3]. The AOFAS Research committee suggests using another PROM than the AOFAS score and states some of its weaknesses: limited precision, difficultly interpretable questions, unreliability, and low levels of correlation when compared to other validated PROMs[4]. The recently introduced EFAS score is a six-item PROM that was developed by the Score committee of European Foot and Ankle Society[26]. The EFAS score addresses the need of language specific validation, and it has been validated in several European languages. Further research including defining the MIC for the EFAS score is warranted in the future. In their comprehensive systematic review, Jia et al identified 115 studies on the measurement properties of 50 different PROMs[4]. Their review found limited scientific evidence of psychometric (measurement) properties on majority of the scores. MIC has been previously defined to at least the following foot and

ankle scores the Manchester oxford foot questionnaire (MOXFQ)[27], the Foot and ankle ability measure (FAAM)[28], the VISA-A[29], the AOFAS[30], the Ankle Osteoarthritis Scale (AOS)[31], the Lower extremity functional scale (LEFS)[32], Self-reported foot and ankle score (SEFAS)[33]. A small portion of foot and ankle PROMs have had their MIC estimated. The number of foot and Ankle PROMs should however be limited, as MIC for each PROM need to be estimated for the most common and important conditions that foot and ankle surgeons treat. Thus, further scientific evidence of measurement properties is needed to compare and to decide on recommendable foot and ankle score.

The current study was conducted with a representative sample of foot and ankle patients that received operative treatment. The limitations of the present study are relatively wide range of clinical diagnoses which on one hand reflects positively on the generalizability of the results and on the other hand does not specify the MICs for a distinct foot or ankle patient group. In the future, MIC for the VAS-FA can be defined specifically for a certain foot and ankle disorder. Nonetheless, the results of the present VWXG\ FDQ EH XVHG WR LQWHUSUHW SDWLHQWV¶ VFRUHV LQ VLPLODU settings. In the future prospective research, the authors recommend using anchor-questions in addition of VAS-FA and to analyze the data to increase the body of evidence of the MICs for the FA-VAS instrument.

5. Conclusions

The VAS-FA efficiently detects change in patients undergoing surgery for foot and ankle disorders. With estimation of the MIC for the VAS-FA, the score can be recommended for use of obtaining information of the clinical change in function, pain and other complaints in patients having undergone surgery for foot and ankle disorders.

Conflict of Interest Statement

Antti J. Saarinen: nothing to disclose.
Mikko M. Uimonen: nothing to disclose.
Henrik Sandelin: nothing to disclose.
Alar Toom: nothing to disclose.
Martinus Richter: nothing to disclose.
Jussi P. Repo: nothing to disclose.

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Figures I–IV. Distributions of the VAS-FA overall and subscale scores in anchor question response category subgroups. The boxes represent median and the whiskers represent interquartile range (IQR).

Figures V ±VIII. Logistic regression models for MIC estimation. The dots on the upper and lower case illustrates the reported outcome of each patient tested. The probability of improvement of 0.83 was used D F F R U G L Q J W R W K H G L V W U L E X W L R Q R I Y D O X H V S D W L H Q W V
The MIC is estimated on the point where the two dotted lines intercept.

Table I. Clinical and sociodemographic characteristics.

Characteristic	Total
Female, n (%)	79 (75)
Age (years), mean (SD, range)	56 (14, 22±80)

BMI, mean (SD, range)	27 (7.6, 18±77)
Education level, n (%)	
Comprehensive scho	35 (33)
Upper secondary school, not gradua	5 (4.7)
Uppersecondary school, graduat	10 (9.4)
Undergraduate degree, not gradua	2 (1.9)
Undergraduate degree, gradua	38 (36)
Graduate degree, not gradua	1 (1)
Graduate degree, graduat	12 (11)
Marital status, n (%)	
In a relationship	9 (8.4)
Married	57 (54)
Never been married	18 (17)
Divorced	10 (9.4)
Widow	10 (9.4)
Duration of symptoms (years), mean (SD, range)	7.8 (9.9, 0.3±50)
Patient-reported health state, n (%)	
Excellent	2 (1.8)
Very good	21 (20)
Good	54 (51)
Moderate	24 (23)
Poor	2 (1.8)
Previous operations, n (%)	46 (43)
Number on previous operations, mean (SD, range)	2 (1.5, 1 ±6)
Patient reported comorbidities, n (%)	
Cardiovascular disease	18 (17)
Diabetes	11 (10)
Hypertension	29 (27)
Rheumatic disease	10 (9.4)
Respiratory disease	16 (15)
Cancer	11 (10)

Table II. Diagnoses and procedures.

Diagnosis	n (%)
Hallux valgus	24 (22.6)
Hallux rigidus	10 (9.4)
Digiti malleiformis	8 (7.5)
Primary osteoarthritis of other joints	6 (5.7)
Post-traumatic osteoarthritis of other joints	5 (4.7)
Fractures of lower leg	3 (2.8)
Pseudarthrosis after join fusion	3 (2.8)
Rheumatoid arthritis with rheumatoid factor	3 (2.8)
Metatarsalgia	3 (2.8)
Pain in joint	3 (2.8)
Other	41 (38.7)

Procedure	n (%)
Fusion of first tarsometatarsal joint	30 (27.9)
Osteotomy or rotation osteotomy of first metatarsal or tarsal bone	13 (12)
Fusion of talocrural joint	7 (6.6)
Operation on fascia, ganglion, synovial sheath or bursa of ankle or foot	6 (5.7)
Removal of internal fixation device from ankle or foot	3 (2.8)
Osteotomy or rotation osteotomy of VI metatarsal or tarsal bone	3 (2.8)
Other	44 (41.5)

Table III. Mean score of change and MIC values for the VAS-FA.

	Mean (SD) score change		Sig.	MIC (95% CI)		Adjusted MIC
	Improved	Not improved				
Total	16.7 (15.6)	1.8 (16.9)	0.002	9.2	(-3.6 to 23.0)	6.8
Pain	22.8 (20.7)	1.6 (19.7)	<0.001	12.4	(-3.5 to 29.5)	9.3
Function	14.9 (16.3)	1.4 (19.6)	0.012	8.3	(-8.2 to 25.1)	5.8
Other	16.4 (21.7)	1.3 (20.9)	0.010	8.9	(-14.2 to 33.7)	5.7

MIC = Minimal important change; 95% CI = 95% confidence interval